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TITLE: Antiretroviral Post-Exposure Prophylaxis

AUTHORS: Puro, V; Ippolito G; the ITALIAN REGISTRY PEP (IRCCS Spallanzani, Rome, Italy)

OBJECTIVE: To monitor the use of antiretroviral post-exposure prophylaxis (PEP) in Italy.

METHODS: Longitudinal, open study conducted by prospective collection of data. In March 1990, the Italian Ministry of Health issued a specific protocol to standardize the indications for and the schedule of ZDV prophylaxis. In November 1996, the protocol was updated to include other antiretroviral drugs (NRTI and PI) in a combination PEP regimen.

RESULTS: Up to December 1998, data were collected on a total of 828 individuals who were treated with ZDV PEP, and 355 who were treated with combination PEP. Most were HCWs who reported occupational exposure; few treatments were done after bite, or fights. An increasing use of PEP after sexual exposures was observed in the last years. In the ZDV-PEP group 1 health care worker seroconverted after conjunctival blood contamination; 51% of individuals reported at least one adverse effect, and 18% discontinued PEP because of side effects (mean 7 days). Most of these constitutional adverse effects were reported in the first week of prophylaxis. Among combination PEP, time from the exposure was 35% within 1 hour, 55% within 2 hours. Among HCWs the highest acceptance rate was less than 35% after percutaneous exposure to known HIV infected source. Mean duration of ~treatment was 15 d in the 2-NRTI group and 18 d in the PI-regimen. At least one side effect was reported in 40% of subjects in the 2-NRTI-group and in 60% in the PI-group. PEP was interrupted <28 days because of adverse reactions in 10% of 2-NRTI treated subjects and 20% of PI-treated subjects after a mean of 10 and 11 days, respectively. One case of transient detection of plasma HIV-1 RNA copies after an occupational exposure to HIV in an uninfected HCW who was treated with combination PEP was observed. Two hypotheses were investigated: false positive result or abortive infection.

CONCLUSIONS: PEP short-term toxicity seems to be mild, and reversible, and not unusual. Frequency of short-term side effects seems to be associated to high dose of ZDV in the monotherapy PEP and to PI in combination PEP. Further studies are needed to assess the risk of major short-term toxicity and of long-term sequelae. People treated with ZDV monotherapy-PEP can be considered as a closed population in whom long-term effects should be evaluated. Among HCWs there is the need to investigate the reasons for acceptance rate lower than expected. A cautious use of biomolecular assays is recommended.

PRESENTER CONTACT INFORMATION

Name: V. Puro

Address: IRCCS L. Spallanzani-via Portuense 292
Roma, I 00149

Telephone: (39) 065594223

Fax: (39) 065594224